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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,557	01/06/2005	Moon-Hee Sung	4240-116	5278

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EXAMINER

HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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10/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,557	Applicant(s) SUNG ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-14,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/10, 6/18/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Note to Applicant: The status identifiers of claims 19 and 20 should be modified to indicate that they are withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 18, 2010 has been entered.

Election/Restrictions

To summarize the current election, applicant elected Group I.

Claims 4-14 and 19-20 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-17 recite properties that are relative to the environment or initial conditions in which the polymer resides, but do not also include details this environment or initial condition. For example, claim 17 recites a calcium solubility for the poly(gamma-glutamate) as a percentage, but a percentage is meaningless without a basis (e.g. the percentage is a fraction of some value or entity, however this "value" or "entity" is not recited in the claim). The measurement and comprehension of this property is wholly dependent on the assay utilized, but none of these testing conditions are recited in the claim. Thus the "at least 46%" has no basis or frame of reference. The instant disclosure does not provide a limiting definition for "calcium solubility", therefore one of ordinary skill in the art could not ascertain the metes and bounds of this claim. Similarly, claims 15 and 16 recite water retention or an increase in water content over 24 hours, but specify no conditions or environment in which this absorption or retention occurs (e.g. the source of the water is not recited). Thus the metes and bounds of these claims also cannot be determined by one of ordinary skill in the art.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Dilorio et al. (previously cited).

Dilorio et al. disclose a gamma-poly(glutamic acid) (also known as poly(gamma glutamate)) (PGA) whose molecular weight is 7,380,000 g/mol ($\pm 1,000,000$ g/mol) which corresponds to 7380 kDa (see page 11 line 32-page 12 line 5 and example V; instant claims 1-2). Since this single molecular weight value is used to describe the polymer, it is interpreted as a mean molecular weight. Instant claims 1-2 recite a product by process, where the claimed polymer is made by a particular bacterial strain. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.’ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). . . . The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing

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process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)” (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. In the instant case, the recitation of the *Bacillus subtilis* var. *chunkookjang* does not add any limitations that affect the patentability of the claimed PGA. Thus the teachings of Dilorio et al. anticipate those of instant claims 1-2. Applicants have provided no evidence distinguishing the PGA derived from their preferred source from the PGA disclosed in Dilorio et al. According to MPEP 2112.01, “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” This treatment results from *In re Spada*, which states that, “Products of identical chemical composition can not have mutually exclusive properties.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The molecular weight of the material of Dilorio et al. meets the limitations of applicants’ claim and therefore their PGA is the same as that instantly claimed and would have the same properties (see instant claims 15-17). Therefore claims 1-2 and 15-17 are unpatentable over Dilorio et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dilorio et al.

Dilorio et al. teach a PGA whose molecular weight is can rage from 2500 kDa to 100,000 kDa (see page 11 line 32-page 12 line 5 and example V). Additional particular

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molecular weights are taught that include 10,000 kDa (see page 12 line 3). In addition, Dilorio et al. also teach that the molecular weight can be obtained using different formulations of broth for the cells that generate the polymer (see example II). Dilorio et al. also teach utilizing purification techniques to separate out defined molecular weight populations with a low polydispersity (range of molecular weights). Further, Dilorio et al. also contemplate routine experimentation to yield variations of the specific embodiments taught as being within the scope of their invention (see page 10 lines 2-7). While Dilorio et al. do not explicitly teach PGA with a mean molecular weight of 13,000, this molecular weight falls within the range taught and would have been achieved as matter of routine experimentation by one of ordinary skill in the art at the time of the invention. Instant claim 18 recites a product by process, where the claimed polymer is made by a particular bacterial strain. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.’ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).....The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276,

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279, 162 USPQ 221, 223 (CCPA 1979)” (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. In the instant case, the recitation of the *Bacillus subtilis* var. *chunkookjang* does not add any limitations that affect the patentability of the claimed PGA. Applicants have provided no evidence distinguishing the PGA derived from their preferred source from PGA disclosed in Dilorio et al. Since a 13,000 kDa PGA would have been obvious from the teachings of Dilorio et al., it would also have the same properties as the PGA instantly claimed given that its structure would be the same as that of the instant invention (see instant claim 18). Therefore claim 18 is obvious over Dilorio et al.

Response to Arguments

Applicants’ arguments and exhibit, filed June 18, 2010, have been fully considered but are not persuasive.

Regarding the rejections under 35 USC 112, second paragraph:

The rejection of claims 1 and 18 under 35 USC 112, second paragraph is hereby withdrawn in light of the amendment to the claims

Applicants argue that instant examples 1-4 provide ample description of the moisture retention, moisture absorbing, and calcium solubility parameters claimed as recited in claims 15-17. In addition, applicants argue that the percentages recited are based upon the baseline measurements described in the examples. Although the claims

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are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examples of the specification are not limiting, thus the conditions under which the claimed parameters are measured/demonstrated in the examples are not read into the claims as definitions or limitations.

Regarding the rejection under 35 USC 102(b):

Applicants argue that the process recited in the product claims under examination impart distinctive structural characteristics to the final product and offer exhibit A as evidence. This data is not proper evidence on the record and is unpersuasive for this reason. According to MPEP 716.02 (g), "The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." In addition, MPEP 716.02 (c) details that "the arguments of counsel cannot take the place of evidence on the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant." Even if considered, the displayed plot of molecular weight distributions of PGA generated by a strain of bacteria as utilized in the instant invention or generated by a strain as taught by

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Dilorio et al. do not demonstrate a structural difference between the PGA of the instant invention and that taught by Dilorio et al. Additionally, Dilorio et al. explicitly teach an example that includes PGA with the claimed mean molecular weight. The information provided by Exhibit A does nothing to refute this teaching or to demonstrate that the polymer instantly claimed has a structure that is different than that taught by Dilorio et al. Although applicants point to examples in Dilorio et al. where fractionation is used to obtain higher molecular weight PGA, while applicants' methodology can yield a higher molecular weight without such fractionation, the instant claims are drawn to a product and not a process. Therefore these arguments concerning the post-fermentation processing of PGA are not relevant to the currently claimed product.

Regarding the rejection under 35 USC 103(a):

Applicants reiterate arguments presented against the teachings of Dilorio et al. in the rejection made under 35 USC 102(b). These arguments were addressed above and the response is similarly reiterated.

The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/

Primary Examiner, Art Unit 1634